

Center For Drug Evaluation and Research

List of Guidance Documents

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Table of Contents (by Subject Category)

Advertising	Page 3
Biopharmaceutics	Page 3
Chemistry	Page 4
Clinical Antimicrobial	Page 7
Clinical Medical	Page 9
Clinical Pharmacology	Page 14
Combination Products (Drug/Device/Biologic)	Page 15
Compliance	Page 15
Current Good Manufacturing Practices	Page 17
Electronic Submissions	Page 17
Generic Drug	Page 18
Good Review Practices	Page 20
ICH	Page 20
IND	Page 24
Industry Letters	Page 25
Labeling	Page 26
OTC	Page 26
Pharmacology/Toxicology	Page 27
Procedural	Page 28
Small Entity Compliance Guides	Page 31
User Fee	Page 31

Advertising

Issued Date

Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling (I)

1/12/1998

Consumer-Directed Broadcast Advertisements (I)

8/9/1999

Industry-Supported Scientific and Educational Activities (I)

12/3/1997

Advertising Draft

Issued Date

"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (I)

2/10/2004

Accelerated Approval Products -- Submission of Promotional Materials (I)

3/26/1999

Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements(I)

2/10/2004

Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling (I)

3/12/1999

Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs) (I)

1/5/1998

Biopharmaceutics

Issued Date

Bioanalytical Method Validation (I)

5/23/2001

Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (Revised) (I)

3/19/2003

Cholestyramine Powder In Vitro Bioequivalence (I)

7/15/1993

Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing (I)

12/30/2003

Corticosteroids, Dermatologic (topical) In Vivo (I)

6/2/1995

Dissolution Testing of Immediate Release Solid Oral Dosage Forms (I)	8/25/1997
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (I)	9/26/1997
Food-Effect Bioavailability and Fed Bioequivalence Studies (I)	1/31/2003
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (I)	6/27/1989
Phenytoin/Phenyton Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	3/4/1994
Statistical Approaches to Establishing Bioequivalence (I)	2/2/2001
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System (I)	8/31/2000

Biopharmaceutics Draft

Issued Date

Antifungal (topical) (I)	2/24/1990
Antifungal (vaginal)	2/24/1990
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action - 2nd Draft (I)	4/3/2003
Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence (I)	3/9/2000

Chemistry

Issued Date

BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation (I)	2/16/2001
Botanical Drug Products (I)	6/9/2004
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (I)	7/24/1997

Changes to an Approved NDA or ANDA (Revised) (I)	4/8/2004
Changes to an Approved NDA or ANDA: Questions and Answers (I)	1/22/2001
Changes to an Approved New Drug Application or Abbreviated New Drug Application; Specifications - Use of Enforcement Discretion for Compendial Changes (I)	11/22/2004
Container Closure Systems for Packaging Human Drugs and Biologics (I)	7/7/1999
Demonstration of Comparability of Human Biological Products Including Therapeutic Biotechnology Derived Products (I)	3/26/1996
Development of New Stereoisomeric Drugs (I)	5/1/1992
Drug Master Files (I)	9/1/1989
Drug Master Files for Bulk Antibiotic Drug Substances (I)	11/29/1999
Environmental Assessment of Human Drug and Biologics Applications (I)	7/27/1998
Format and Content for the CMC Section of an Annual Report (I)	9/1/1994
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application* (I)	2/1/1987
Format and Content of the Microbiology Section of an Application* (I)	2/1/1987
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information (I)	5/25/2001
INDs for Phase 2 and 3 Studies; Chemistry, Manufacturing, and Controls Information (I)	5/20/2003
Monoclonal Antibodies Used as Reagents in Drug Manufacturing (I)	3/29/2001
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products -- Chemistry, Manufacturing, and Controls Documentation (I)	7/5/2002

NDA: Impurities in Drug Substances (I)	2/25/2000
PAC-ALTS: Postapproval Changes - Analytical Testing Laboratory Sites (I)	4/28/1998
Submission Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products (I)	11/1/1994
Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances (I)	11/1/1994
Submitting Documentation for the Manufacturing of and Controls for Drug Products* (I)	2/1/1987
Submitting Documentation for the Stability of Human Drugs and Biologics* (I)	2/1/1987
Submitting Samples and Analytical Data for Methods Validation* (I)	2/1/1987
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products (I)	2/1/1987
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances* (I)	2/1/1987
SUPAC-IR Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (I)	11/30/1995
SUPAC-IR Questions and Answers (I)	2/18/1997
SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum (I)	2/26/1999
SUPAC-MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (I)	10/6/1997
SUPAC-SS - Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (I)	6/13/1997
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform (I)	12/20/2000
Validation of Chromatographic Methods -- Reviewer's Guidance (I)	11/1/1994

Chemistry Draft

Issued Date

Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation (I)	8/30/2000
ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Informational (I)	12/20/2004
Comparability Protocols - Chemistry, Manufacturing, and Controls Information (I)	2/25/2003
Drug Product: Chemistry, Manufacturing, and Controls Information (I)	1/28/2003
Drug Substance: Chemistry, Manufacturing, and Controls Information (I)	1/7/2004
Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals (I)	9/12/2002
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (I)	7/26/1999
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation (I)	8/21/2002
Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation (I)	11/19/1998
Stability Testing of Drug Substances and Drug Products (I)	6/8/1998
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications*	11/1/1991
SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (I)	1/5/1999

Clinical Antimicrobial

Issued Date

Antiretroviral Drugs Using Plasma Human Immunodeficiency Virus Ribonucleic Acid Measurements - Clinical Considerations for Accelerated and Traditional Approval (I)	11/1/2002
Clinical Development and Labeling of Anti-Infective Drug Products (I)	10/26/1992

Clinical Evaluation of Anti-Infective Drugs (Systemic) (I)	9/1/1977
Preclinical Development of Antiviral Drugs (I)	11/1/1990

Clinical Antimicrobial Draft

Issued Date

Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment (I)	10/18/1999
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Developing Antimicrobial Drugs -General Considerations for Clinical Trials (I)	7/22/1998
Developing Drugs to Treat Inhalational Anthrax (Post-Exposure) (I)	3/18/2002
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products (I)	2/17/1997

Lyme Disease; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Role of HIV Drug Resistance Testing in Antiretroviral Drug Development (I)	11/29/2004
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Uncomplicated Gonorrhea -- Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Vaccinia Virus -- Developing Drugs to Mitigate Complications From Smallpox Vaccination (I)	3/9/2004
Vulvovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998

Clinical Medical

Issued Date

Acceptance of Foreign Clinical Studies (I)	3/13/2001
Antianxiety Drugs -- Clinical Evaluation (I)	9/1/1977
Antidepressant Drugs -- Clinical Evaluation (I)	9/1/1977
Antiepileptic Drugs (adults and children) -- Clinical Evaluation (I)	1/1/1981
Anti-Inflammatory and Antirheumatic Drugs (adults and children) -- Clinical Evaluation (I)	4/1/1988

Available Therapy (I)	7/23/2004
Calcium DTPA and Zinc DTPA Drug Products -- Submitting a New Drug Application (I)	8/13/2004
Cancer Drug and Biological Products - Clinical Data in Marketing Applications (I)	10/5/2001
Clinical and Statistical Sections of an Application -- Format and Content* (I)	7/1/1988
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (I)	2/17/1999
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I)	11/20/1995
Developing Medical Imaging Drug and Biological Products, Part 1: Conducting Safety Assessments (I)	6/22/2004
Developing Medical Imaging Drug and Biological Products, Part 2: Clinical Indications (I)	6/22/2004
Developing Medical Imaging Drug and Biological Products, Part 3: Design, Analysis, and Interpretation of Clinical Studies (I)	6/22/2004
Development and Use of Risk Minimization Action Plans (I)	3/29/2005
Development of Vaginal Contraceptive Drugs (NDA) (I)	4/19/1995
Establishing Pregnancy Exposure Registries (I)	9/23/2002
Evaluating the Risks of Drug Exposure in Human Pregnancies	4/28/2005
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (I)	2/2/1999
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer (I)	1/29/1991
Formatting, Assembling and Submitting New Drug and Antibiotic Applications* (I)	2/1/1987

General Anesthetics -- Clinical Evaluation (I)	5/1/1982
General Considerations for the Clinical Evaluation of Drugs (I)	12/1/1978
General Considerations for the Clinical Evaluation of Drugs in Infants and Children (I)	9/1/1977
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (I)	3/29/2005
Hypnotic Drugs -- Clinical Evaluation (I)	9/1/1977
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (Revised) (I)	1/15/2004
Integration of Dose-Counting Mechanisms Into Metered-Dose Inhaler Drug Products (I)	3/13/2003
Levothyroxine Sodium Tablets -- In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing (I)	3/8/2001
Local Anesthetics -- Clinical Evaluation (I)	5/1/1982
MDI and DPI Drug Products -- Clinical Development and Programs (I)	9/19/1994
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer (I)	4/19/1988
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer (I)	4/13/1988
Pediatric Use Supplements -- Content and Format (I)	5/24/1996
Postmarketing Adverse Experience Reporting for Human Drugs and Licensed Biological Products; Clarification of What to Report (I)	8/27/1997
Postmarketing Reporting of Adverse Drug Experiences (I)	3/1/1992
Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders (I)	9/4/1992

Premarketing Risk Assessment (I)	3/29/2005
Preparation of Investigational New Drug Products (Human and Animal) (I)	11/1/1992
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (I)	5/15/1998
Prussian Blue for Treatment of Internal Contamination With Thallium or Radioactive Cesium (I)	2/4/2003
Psychoactive Drugs in Infants and Children -- Clinical Evaluation (I)	7/1/1979
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (I)	7/22/1993
Study of Drugs Likely to be Used in the Elderly (I)	11/1/1989
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (I)	9/13/1999
Summary for New Drug and Antibiotic Applications -- Format and Content* (I)	2/1/1987

Clinical Medical Draft

Issued Date

Abuse Liability Assessment (I)	7/1/1990
Allergic Rhinitis: Clinical Development Programs for Drug Products (I)	6/21/2000
Anti-Anginal Drugs -- Clinical Evaluation (I)	1/1/1989
Anti-Arrhythmic Drugs -- Clinical Evaluation	7/1/1985
Antihypertensive Drugs -- Clinical Evaluation	5/1/1988
Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment (I)	6/28/2000

Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA) (I)	7/15/1999
Clinical Endpoints for the Approval of Cancer Drugs and Biologics	4/4/2005
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure (I)	12/1/1987
Clinical Lactation Studies - Study Design, Data Analysis and Recommendations for Labeling	2/8/2005
Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees (I)	11/20/2001
Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products (I)	1/30/2003
Combination Products Timeliness of Premarket Reviews (I)	5/4/2004
Computerized Systems Used in Clinical Trials (I)	10/4/2004
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders	2/12/1992
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis (I)	6/14/2000
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals	9/12/2002
Estrogen and Estrogen/ Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Recommendations for Clinical Evaluation (Revised) (I)	1/31/2003
Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children (I)	11/6/2001
Exercise-Induced Bronchospasm (EIB) - Development of Drugs to Prevent EIB (I)	2/20/2002
Exocrine Pancreatic Insufficiency Drug Products-Submitting New Drug Applications (I)	4/28/2004
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment (I)	5/19/2000

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (I)	3/30/2000
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (I)	7/26/2002
Internal Radioactive Contamination - Development of Decorporation Agents (I)	2/15/2005
Lipid-Altering Agents in Adults and Children -- Clinical Evaluation (I)	9/1/1990
OTC Treatment of Herpes Labialis with Antiviral Agents (I)	3/8/2000
Pediatric Oncology Studies in Response to a Written Request (I)	6/21/2000
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (I)	4/1/1994
Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals	9/1/1991
Recommendations for Complying with the Pediatric Rule (I)	12/4/2000
Systemic Lupus Erythematosus - Developing Drugs for Treatment (I)	3/29/2005
The Use of Clinical Holds Following Clinical Investigator Misconduct (I)	9/2/2004
Weight-Control Drugs -- Clinical Evaluation (I)	9/24/1996

Clinical Pharmacology

Issued Date

Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (I)	4/7/1997
Exposure-Response Relationships - Study Design, Data Analysis, and Regulatory Applications (I)	5/6/2003
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (I)	2/1/1987

In Vivo Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling (I)	11/24/1999
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Pharmacogenomic Data Submissions	3/23/2005
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Pharmacokinetics in Patients With Impaired Hepatic Function; Study Design, Data Analysis, and Impact on Dosing and Labeling (I)	5/30/2003
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Pharmacokinetics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (I)	5/15/1998
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Population Pharmacokinetics (I)	2/10/1999
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Clinical Pharmacology Draft

Issued Date

General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (I)	11/30/1998
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Pharmacokinetics in Pregnancy - Study Design, Data Analysis, and Impact on Dosing and Labeling (I)	11/1/2004
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Combination Products (Drug/Device/Biologic)

Issued Date

Application User Fees for Combination Products	4/21/2005
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Combination Products (Drug/Device/Biologic) Draft

Issued Date

Combination Products Timeliness of Premarket Reviews; Dispute Resolution (I)	5/4/2004
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Current Good Manufacturing Practices for Combination Products (I)	10/4/2004
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Compliance

Issued Date

A Review of FDA's Implementation of the Drug Export Amendments of 1986 (I)	5/1/1990
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Compressed Medical Gases (I)	12/1/1989
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Computerized Systems Used in Clinical Trials (I)	5/10/1999
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Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (I)	6/27/1997
General Principles of Process Validation (I)	5/1/1987
Good Laboratory Practice Regulations -- Questions and Answers (I)	6/1/1981
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities (I)	4/6/2001
Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices (I)	12/1/1987
Monitoring of Clinical Investigations (I)	1/1/1988
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (I)	5/1/1984
Pharmacy Compounding -- Compliance Policy Guide (I)	6/7/2002
Possible Dioxin/PCB Contamination of Drug and Biological Products (I)	8/23/1999
Sterile Drug Products Produced by Aseptic Processing (I)	5/1/1987
Street Drug Alternatives (I)	4/3/2000

Compliance Draft

Issued Date

Current Good Manufacturing Practices for Medical Gases (3rd Revision) (I)	5/6/2003
Good Manufacturing Practice for Positron Emission Tomography Drug Products (I)	4/1/2002
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (I)	5/12/2000
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (I)	9/30/1998

Manufacture, Processing or Holding of Active Pharmaceutical Ingredients (I)	4/17/1998
Marketed Unapproved Drugs; Compliance Policy Guide (I)	10/23/2003
Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics (I)	6/27/2002
Repackaging of Solid Oral Dosage Form Drug Products	2/1/1992

Current Good Manufacturing Practices

Issued Date

Part 11, Electronic Records, Electronic Signatures - Scope and Application	9/5/2003
Process Analytical Technology -- A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance (I)	10/4/2004
Sterile Drug Products Produced by Aseptic Processing (I)	10/4/2004

Current Good Manufacturing Practices Draft

Issued Date

Comparability Protocols -- Protein Drug Products and Biological Products -- Chemistry, Manufacturing, and Controls Information (I)	9/5/2003
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practices (I)	9/5/2003
Powder Blends and Finished Dosage Units--Stratified In-Process Dosage Unit Sampling and Assessment (I)	11/7/2003
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (I)	10/4/2004

Electronic Submissions

Issued Date

Providing Electronic Submissions in Electronic Format - ANDAs (I)	6/27/2002
Providing Regulatory Submissions in Electronic Format -- Content of Labeling (I)	4/21/2005
Regulatory Submissions in Electronic Format; General Considerations (I)	1/28/1999

Regulatory Submissions in Electronic Format; NDAs (I)

1/28/1999

Electronic Submissions Draft

Issued Date

Providing Regulatory Submissions in Electronic Format -- Annual Reports for New Drug Applications and Abbreviated New Drug Applications (I)

8/28/2003

Providing Regulatory Submissions in Electronic Format -- Human Pharmaceutical Applications and Related Submissions (I)

8/29/2003

Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports (I)

5/4/2001

Providing Regulatory Submissions in Electronic Format -- Postmarketing Periodic Adverse Drug Experience Reports (I)

6/24/2003

Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling (I)

1/31/2001

Providing Regulatory Submissions in Electronic Format--General Considerations (I)

10/22/2003

Generic Drug

Issued Date

180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day (I)

8/1/2003

Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs (I)

12/12/2000

ANDAs: Impurities in Drug Substances (I)

12/3/1999

Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I)

3/30/2000

Handling and Retention of Bioavailability and Bioequivalence Testing Samples (I)

5/26/2004

Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past (I)

8/18/1995

Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process (I)

10/14/1994

Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy (I)	4/8/1994
Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters (I)	7/1/1992
Letter on the provision of new procedures and policies affecting the generic drug review process (I)	3/15/1989
Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions (I)	11/8/1991
Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act (I)	3/26/1985
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law (I)	1/15/1993
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements (I)	8/4/1993
Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications (I)	12/21/2001
Organization of an ANDA (I)	3/2/1999
Revising ANDA Labeling Following Revision of the RLD Labeling (I)	4/25/2000
Variations in Drug Products that May Be Included in a Single ANDA (I)	1/27/1999

Generic Drug Draft

Issued Date

ANDAs: Impurities in Drug Products (I)	1/5/1999
Listed Drugs, 30-Month Stays, and Approval of Abbreviated New Drug Applications and 505 (b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug Improvement, and Modernization Act of 2003, Questions and Answers (I)	11/4/2004
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (Revised)(I)	8/7/2002

Generics Draft

Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing and Controls Information

Issued Date

1/31/2005

Good Review Practices

Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (I)

2/18/2005

Good Review Management Principles for Prescription Drug User Fee Act Products (I)

3/31/2005

Pharmacology/Toxicology Review Format (I)

5/10/2001

ICH - Efficacy

Issued Date

E10 - Choice of Control Group and Related Issues in Clinical Trials (I)

5/14/2001

E11 - Clinical Investigation of Medicinal Products in the Pediatric Population (I)

12/15/2000

E1A - The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions (I)

3/1/1995

E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (I)

3/1/1995

E2B - Data Elements for Transmission of Individual Case Safety Reports (I)

1/15/1998

E2B(M) - Data Elements for Transmission of Individual Case Safety Reports (Revised) (I)

4/3/2002

E2B(M): Data Elements for Transmission of Individual Case Safety Reports -- Questions and Answers (Revision 2) (I)

3/9/2005

E2C - Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I)

5/19/1997

E2C Addendum - Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I)

2/5/2004

E2E - Pharmacovigilance Planning (I)

4/1/2005

E3 - Structure and Content of Clinical Study Reports (I)	7/17/1996
E4 - Dose-Response Information to Support Drug Registration (I)	11/9/1994
E5 - Ethnic Factors in the Acceptability of Foreign Clinical Data (I)	6/10/1998
E5 - Ethnic Factors in the Acceptability of Foreign Clinical Data, Questions and Answers (I)	6/4/2004
E6 - Good Clinical Practice: Consolidated Guideline (I)	5/9/1997
E7 - Studies in Support of Special Populations: Geriatrics (I)	8/2/1994
E8 - General Considerations for Clinical Trials (I)	12/24/1997
E9 - Statistical Principles for Clinical Trials (I)	9/16/1998

ICH - Joint Safety/Efficacy (Multidisciplinary)

Issued Date

M2 - Electronic Common Technical Document Specification (eCTD) (I)	3/11/2005
M3 - Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (I)	11/25/1997
M4 - Organization of the Common Technical Document (CTD) (I)	10/16/2001
M4 - The CTD -- Efficacy Questions and Answers (Revised) (I)	12/22/2004
M4 - The CTD -- General Questions and Answers (Revised) (I)	12/22/2004
M4 - The CTD - Quality Questions and Answers/Location Issues (I)	6/9/2004
M4 - The CTD -- Safety Questions and Answers (I)	2/4/2003

ICH - Joint Safety/Efficacy (Multidisciplinary) Draft

Issued Date

Submitting Marketing Applications According to the ICH/CTD Format; General Considerations (I)

9/5/2001

ICH - Quality

Issued Date

Q1A(R2) - Stability Testing of New Drug Substances and Products (I)

11/21/2003

Q1B - Photostability Testing of New Drug Substances and Products (I)

5/16/1997

Q1C - Stability Testing for New Dosage Forms (I)

5/9/1997

Q1D - Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (I)

1/16/2003

Q1E - Evaluation of Stability Data (I)

6/8/2004

Q1F - Stability Data Package for Registration in Climatic Zones III and IV (I)

7/1/2004

Q2A - Text on Validation of Analytical Procedures (I)

3/1/1995

Q2B - Validation of Analytical Procedures: Methodology (I)

5/9/1997

Q3A(R) - Impurities in New Drug Substances (I)

2/11/2003

Q3B(R) - Impurities in New Drug Products (I)

11/14/2003

Q3C - Impurities: Residual Solvents (I)

12/24/1997

Q3C - Tables and Lists (Revised) Recommendations for Methylpyrrolidone and Tetrahydrofuran (I)

11/13/2003

Q5A - Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (I)

9/24/1998

Q5B - Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products (I)	2/23/1996
Q5C - Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products (I)	7/10/1996
Q5D - Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products (I)	9/21/1998
Q6A - Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (I)	12/29/2000
Q6B - Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (I)	8/18/1999
Q7A - Good Manufacturing Practice for Active Pharmaceutical Ingredients (I)	9/25/2001

ICH - Safety

Issued Date

ICH S8 Immunotoxicity Studies for Human Pharmaceuticals (I)	2/8/2005
S1A - The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals (I)	3/1/1996
S1B - Testing for Carcinogenicity in Pharmaceuticals (I)	2/23/1998
S1C - Dose Selection for Carcinogenicity Studies of Pharmaceuticals (I)	3/1/1995
S1C(R) - Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (I)	12/4/1997
S2A - Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals (I)	4/24/1996
S2B - Genotoxicity: Standard Battery Testing (I)	11/21/1997
S3A - Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (I)	3/1/1995
S3B - Pharmacokinetics: Repeated Dose Tissue Distribution Studies (I)	3/1/1995

S4A - Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) (I)	6/25/1999
S5A - Detection of Toxicity to Reproduction for Medicinal Products (I)	9/22/1994
S5B - Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (I)	4/5/1996
S6 - Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (I)	11/18/1997
S7A - Safety Pharmacology Studies for Human Pharmaceuticals (I)	7/13/2001

ICH Draft - Efficacy

Issued Date

E12A Principles for Clinical Evaluation of New Antihypertensive Drugs (I)	8/9/2000
E14 - Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	9/13/2004
E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (I)	9/15/2003
E2E - Pharmacovigilance Planning (PvP) (I)	3/30/2004

ICH Draft - Quality

Issued Date

Q5E - Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process (I)	3/30/2004
Q8 Pharmaceutical Development	2/9/2005

ICH Draft - Safety

Issued Date

S7B - Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (I)	6/14/2002
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INDs

Issued Date

Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I)	10/4/2000
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Industry Letters

Issued Date

A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	7/15/1996
Certification Requirements for Debarred Individuals in Drug Applications	6/1/1990
Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program (I)	3/2/1998
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required (I)	4/10/1987
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I (I)	10/31/1986
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance (I)	10/11/1984
Implementation Plan USP injection nomenclature (I)	10/2/1995
Instructions for Filing Supplements Under the Provisions of SUPAC-IR	4/11/1996
Seventh of a series of letters about the Act providing guidance on the "180-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C (I)	7/29/1988
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act (I)	4/28/1988
Streamlining Initiatives	12/24/1996
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format) (I)	11/16/1984
Third of a series of letters regarding the implementation of the Act (I)	5/1/1985
Year 2000 Letter from Dr. Janet Woodcock (I)	10/19/1998

Labeling

Issued Date

Barbiturate, Single Entity-Class Labeling

3/1/1981

Content and Format for Geriatric Labeling (I)

10/5/2001

Hypoglycemic Oral Agents - Federal Register

4/1/1984

Labeling Over-the-Counter Human Drug Products; Updating Labeling In Reference Listed Drugs and Abbreviated New Drug Applications (I)

10/18/2002

Local Anesthetics - Class Labeling

9/1/1982

Labeling Draft

Issued Date

Clinical Studies Section of Labeling for Prescription Drugs and Biologics; Content and Format (I)

7/9/2001

Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics (I)

6/21/2000

Labeling for Combined Oral Contraceptives (I)

3/5/2004

Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms -- Prescribing Information for Health Care Providers and Patient Labeling (I)

2/17/2004

OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (I)

7/16/1998

Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (I)

10/26/2000

OTC

Issued Date

Enforcement Policy on Marketing OTC Combination Products (CPG 71320.16) (I)

5/1/1984

General Guidelines for OTC Combination Products (I)

11/28/1978

Labeling OTC Human Drug Products -- Updating Labeling in ANDAs (I)

2/22/2001

Labeling OTC Human Drug Products Using a Column Format (I)	12/19/2000
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Labeling Over-the-Counter Human Drug Products; Questions and Answers	1/13/2005
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Upgrading Category III Antiperspirants to Category I (43 FR 46728 - 46731) (I)	10/10/1978
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OTC Draft

Issued Date

Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals (I)	12/19/2000
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OTC Actual Use Studies	7/22/1994
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OTC Nicotine Substitutes	3/1/1994
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Small Business Entities on Labeling Over-the-Counter Human Drug Products (I)	12/9/2004
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Time and Extent Applications (I)	2/10/2004
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Pharmacology/Toxicology

Issued Date

Carcinogenicity Study Protocol Submissions (I)	5/23/2002
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Format and Content of the Nonclinical Pharmacology/ Toxicology Section of an Application (I)	2/1/1987
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Immunotoxicology Evaluation of Investigational New Drugs (I)	11/1/2002
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Nonclinical Pharmacology/Toxicology Department of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or the Development of Drugs Intended to Act as Vaginal Contraceptives (I)	10/16/1996
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Photosafety Testing (I)	5/7/2003
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Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (I)	2/1/1989
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Pharmacology/Toxicology Draft**Issued Date**

Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers (I)

1/16/2003

Exploratory IND Studies (I)

4/12/2005

Integration of Study Results to Address Concerns About Human Reproductive and Developmental Toxicities

11/13/2001

Nonclinical Safety Evaluation of Drug Combinations (I)

1/26/2005

Nonclinical Safety Evaluation of Pediatric Drug Products (I)

2/3/2003

Nonclinical Studies for Development of Pharmaceutical Excipients (I)

10/2/2002

Recommended Approaches to Integration of Genetic Toxicology Study Results (I)

12/2/2004

Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals (I)

5/8/2001

Procedural**Issued Date**

180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I)

7/14/1998

Continuous Marketing Applications: Pilot 1--Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act of 1992 (I)

10/6/2003

Continuous Marketing Applications: Pilot 2--Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992 (I)

10/6/2003

Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act

3/27/2000

Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 (I)

11/30/1999

Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate - Labeling Enforcement Policy (I)	6/3/2003
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act (I)	11/23/1998
Fast Track Drug Development Programs: Designation, Development, and Application Review (I)	11/18/1998
FDA Export Certificate (I)	7/12/2004
Financial Disclosure by Clinical Investigators (I)	3/28/2001
Formal Dispute Resolution: Appeals Above the Division Level (I)	3/7/2000
Formal Meetings With Sponsors and Applicants For PDUFA Products (I)	3/7/2000
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997- Elimination of Certain Labeling Requirements (I)	11/2/1998
Implementation of Section 126 of the FDA Modernization Act of 1997 - Elimination of Certain Labeling Requirements, (I)	7/21/1998
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I)	3/18/2002
Levothyroxine Sodium Products - Enforcement of August 14, 2001, Compliance Date and Submission of New Applications (I)	7/13/2001
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs (I)	4/9/1998
Potassium Iodide (KI) in Radiation Emergencies - Questions and Answers (I)	12/23/2002
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (I)	12/11/2001
Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments (I)	3/8/2004
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act - Revised (I)	10/1/1999

Refusal to File (I)	7/12/1993
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act (I)	6/15/1998
Special Protocol Assessment (I)	5/17/2002
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements (I)	5/15/1998
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (I)	10/26/2000
The Leveraging Handbook; an Agency Resource for Effective Collaborations - Guidance for FDA Staff (I)	6/19/2003
Women and Minorities Guidance Requirements	7/20/1998

Procedural Draft

Issued Date

Applications Covered by Section 505(b)(2) (I)	12/8/1999
Centralized IRB Review Proceedings in Multicenter Clinical Trials	3/23/2005
Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees (I)	11/15/2001
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products (I)	3/10/2000
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000 (I)	12/22/1999
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees	2/14/2002
Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV (I)	5/19/2004
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (I)	5/15/2001

Good Review Management Principles for PDUFA Products (I)	7/28/2003
Independent Consultants for Biotechnology Clinical Trial Protocols (I)	5/7/2003
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I)	1/27/2004
Pharmacogenomic Data Submissions (I)	11/4/2003
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (I)	3/12/2001
Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (I)	4/4/2001
Submitting Debarment Certification Statements (I)	10/2/1998
The Use of Clinical Holds Following Clinical Investigator Misconduct (I)	8/27/2002

Small Entity Compliance Guides

Issued Date

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (I)	11/7/2001
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User Fee

Issued Date

Applicability of User Fees to (1) Applications Withdrawn Before Filing, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F)	7/12/1993
Application, Product, and Establishment Fees: Common Issues and Their Resolution (Revised) (Attachment D) (I)	12/16/1994
Classifying Resubmissions in Response to Action Letters (I)	5/14/1998
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act (I)	8/25/1999
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (I)	11/21/2001

Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (I)

1/3/2005

User Fee Draft

Issued Date

Document for Waivers of and Reductions in User Fees (Attachment G)

7/16/1993

User Fees Draft

Issued Date

User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (I)

4/18/2005